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PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:

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PCT

NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(PCT Rule 71.1)

Date of mailing *(day/month/year)*	24.07.2006
Applicant's or agent's file reference	**IMPORTANT NOTIFICATION**
445/04393	

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/IL2005/000303	17.03.2005	18.03.2004

Applicant
CONTIPI LTD. et al.

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary report on patentability and its annexes, if any, established on the international application.

2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.

3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.

4. **REMINDER**

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary report on patentability. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

The applicant's attention is drawn to Article 33(5), which provides that the criteria of novelty, inventive step and industrial applicability described in Article 33(2) to (4) merely serve the purposes of international preliminary examination and that "any Contracting State may apply additional or different criteria for the purposes of deciding whether, in that State, the claimed inventions is patentable or not" (see also Article 27(5)). Such additional criteria may relate, for example, to exemptions from patentability, requirements for enabling disclosure, clarity and support for the claims.

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25 JUL 2006
To: MK ✓ MF
PO
FENSTER & Co.

Name and mailing address of the international preliminary examining authority:

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PATENT COOPERATION TREATY

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INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 445/04393	**FOR FURTHER ACTION**	See Form PCT/IPEA/416
International application No. PCT/IL2005/000303	International filing date *(day/month/year)* 17.03.2005	Priority date *(day/month/year)* 18.03.2004
International Patent Classification (IPC) or national classification and IPC INV. A61F2/00		
Applicant CONTIPI LTD. et al.		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 8 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
   a. ☒ *sent to the applicant and to the International Bureau)* a total of 5 sheets, as follows:
      ☒ sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
      ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
   b. ☐ *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in electronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:

- ☒ Box No. I Basis of the report
- ☐ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☒ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☒ Box No. VIII Certain observations on the international application

Date of submission of the demand 26.01.2006	Date of completion of this report 24.07.2006
Name and mailing address of the international preliminary examining authority: European Patent Office - P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Tx: 31 651 epo nl Fax: +31 70 340 - 3016	Authorized officer Mary, C Telephone No. +31 70 340-4409

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/IL2005/000303

Box No. I Basis of the report

1. With regard to the **language**, this report is based on

   ☒ the international application in the language in which it was filed

   ☐ a translation of the international application into , which is the language of a translation furnished for the purposes of:

   - ☐ international search (under Rules 12.3(a) and 23.1(b))
   - ☐ publication of the international application (under Rule 12.4(a))
   - ☐ international preliminary examination (under Rules 55.2(a) and/or 55.3(a))

2. With regard to the **elements*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

Description, Pages	
1-18	as originally filed
Claims, Numbers	
1-38	filed with telefax on 10.07.2006
Drawings, Sheets	
1/20-20/20	as originally filed

   ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing

3. ☐ The amendments have resulted in the cancellation of:
   - ☐ the description, pages
   - ☐ the claims, Nos.
   - ☐ the drawings, sheets/figs
   - ☐ the sequence listing *(specify)*:
   - ☐ any table(s) related to sequence listing *(specify)*:

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
   - ☐ the description, pages
   - ☐ the claims, Nos.
   - ☐ the drawings, sheets/figs
   - ☐ the sequence listing *(specify)*:
   - ☐ any table(s) related to sequence listing *(specify)*:

* *If item 4 applies, some or all of these sheets may be marked "superseded."*

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

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Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application,

☒ claims Nos. 12-38

because:

☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination *(specify)*:

☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. are so unclear that no meaningful opinion could be formed *(specify)*:

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed *(specify)*.

☒ no international search report has been established for the said claims Nos. 12-38

☐ a meaningful opinion could not be formed without the sequence listing; the applicant did not, within the prescribed time limit:

☐ furnish a sequence listing on paper complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Preliminary Examining Authority in a form and manner acceptable to it.

☐ furnish a sequence listing in electronic form complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Preliminary Examining Authority in a form and manner acceptable to it.

☐ pay the required late furnishing fee for the furnishing of a sequence listing in response to an invitation under Rules 13*ter*.1(a) or (b) and 13*ter*.2.

☐ a meaningful opinion could not be formed without the tables related to the sequence listings; the applicant did not, within the prescribed time limit, furnish such tables in electronic form complying with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions, and such tables were not available to the International Preliminary Examining Authority in a form and manner acceptable to it.

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in electronic form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.

☐ See separate sheet for further details

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

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Box No. IV Lack of unity of invention

1. ☒ In response to the invitation to restrict or pay additional fees, the applicant has, within the applicable time limit:

   ☐ restricted the claims.

   ☐ paid additional fees.

   ☐ paid additional fees under protest and, where applicable, the protest fee.

   ☐ paid additional fees under protest but the applicable protest fee was not paid.

   ☒ neither restricted the claims nor paid additional fees.

2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is:

   ☒ complied with.

   ☐ not complied with for the following reasons:

4. Consequently, this report has been established in respect of the following parts of the international application:

   ☐ all parts.

   ☒ the parts relating to claims Nos. 1-11 .

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1-11
	No:	Claims	
Inventive step (IS)	Yes:	Claims	1-11
	No:	Claims	
Industrial applicability (IA)	Yes:	Claims	1-11
	No:	Claims	

2. Citations and explanations (Rule 70.7):

   see separate sheet

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

Re Item III.

Rule 39.1(iv) and Rule 67.1 (iv) PCT - Method for treatment of the human or animal body by therapy: Claims 33-38 disclose a method of treating pelvic organ prolapse which is a method of treatment by therapy.

Re Item IV.

The separate inventions are:
- Claims 1-11: an apparatus for treating pelvic organ prolapse comprising a main body and an applicator
- Claims 12-22: an apparatus for treating pelvic organ prolapse comprising a main body and an anchoring body
- Claims 23-32: an apparatus for treating pelvic organ prolapse comprising a thin body which is deformable at least three points thereon.

They are not so linked as to form a single general inventive concept (Rule 13.1 PCT) for the following reasons: the document EP0933069 cited in our search report discloses an apparatus for treating pelvic organ prolapse comprising a main body and an applicator. Beyond this prior art, the special technical features (in the meaning of Rule 13.2 of the P.C.T) left in the independant claims of the application are:
- In independant claim 1: none.
- In independant claim 12: an apparatus for treating pelvic organ prolapse comprising a main body and an anchoring body.
- In independant claim 23: an apparatus for treating pelvic organ prolapse comprising a thin body which is deformable at least three points thereon.

No same or correspondent special technical feature can be found between claim 1 and claims 12 and 23. There is therefore no technical relationship involving same or corresponding special technical features between claim 1 and claims 12 and 23. In conclusion, the groups of claims are not linked by common or corresponding special technical features and define 3 different inventions not linked by a single general inventive concept. The application, hence does not meet the requirements of unity of invention as defined in Rules 13.1 and 13.2 PCT.

Re Item V.

1 Reference is made to the following documents:
D5: EP0274762 (Fortune Capital Management) 20 July 1988 (1988-07-20)
The documents D5 was not cited in the international search report. A copy of the documents is appended hereto.

2 The document D5 is regarded as being the closest prior art to the subject-matter of claim 1 and discloses an apparatus for treating pelvic organ prolapse, comprising a ring shaped main body sized and shaped to apply appropriate pressure on lateral vaginal walls for treating pelvic organ prolapse, the ring shaped main body being flexible.

3 The subject-matter of claim 1 thus differs from this disclosure in that the device is foldable at least three different points or along at least two axes, such that insertion of the main body does not have to be precise and that the ring shaped main body naturally settles into the appropriate rotational position for prolapse treatment taking a pre-defined multi-planar shape; and that the device also comprises an applicator enclosing the ring shaped main body for inserting said ring shaped main body into a vagina.

Therefore the subject-matter of claim 1 is new and meets the requirements of Art.33(2)PCT.

4 These features serve to insert easily the ring-shaped main body, without having to be precise in respect to the rotational angle of the applicator (and the ring-shaped main body) to the vaginal opening. None of the available prior art documents suggests the combination of said features. In particular, the device described in D5 is hand-deformable, but would, if deformed and inserted into an applicator, stay after insertion in its collapsed state.

Therefore claim 1 involves an inventive step and meets the requirements of Art.33(3)PCT.

5 The device disclosed in claim 1 is industrially manufacturable and therefore the claim meets the requirements of Art. 33(4)PCT.

6 Claims 2 to 11 refer to further embodiments of the device of claim 1 and in view of that meet the requirements of Art. 33(2), (3), and (4) PCT as well.

Re Item VIII.

7 Independent claim 1 is in the two-part form in accordance with Rule 6.3(b) PCT, which in the present case is appropriate, with those features known in combination from the prior art (D5) being placed in the preamble (Rule 6.3(b)(i) PCT) and with the remaining features being included in the characterising part (Rule 6.3(b)(ii) PCT). In the present case, the following features are known in combination from the document D5 and belong in the preamble of such a claim:
"An apparatus for treating pelvic organ prolapse, comprising a ring shaped main body sized and shaped to apply appropriate pressure on lateral vaginal walls for treating pelvic organ prolapse, *the ring shaped main body being flexible*."

8 The features of the claims are not provided with reference signs placed in parentheses (Rule 6.2(b) PCT).

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CLAIMS

1. An apparatus for treating pelvic organ prolapse, comprising:

a ring shaped main body sized and shaped to apply appropriate pressure on lateral vaginal walls for treating pelvic organ prolapse,

characterized in that the ring shaped main body is flexible, the device being foldable at at least three different points or along at least two axes, such that insertion of the main body does not have to be precise and that the ring shaped main body naturally settles into the appropriate rotational position for prolapse treatment taking a pre-defined multi-planar shape; and,

an applicator enclosing the ring shaped main body for inserting said ring shaped main body into a vagina.

2. An apparatus according to claim 1 wherein said multi-planar main body extends in three axes.

3. An apparatus according to claims 1 or 2 further comprising a device displacer.

4. An apparatus according to any of claims 1-3 further comprising a soft external layer located on at least a portion of said main body, said soft external layer adapted to enhance comfort.

5. An apparatus according to any of claims 1-4 further comprising a soft external layer located on at least a portion of said main body, said soft external layer adapted to prevent necrosis.

6. An apparatus according to claims 4 or 5 wherein the soft external layer is comprised of sponge rubber.

7. An apparatus according to any of claims 1-6 wherein said apparatus is at least partially flexible, said apparatus flexible in response to forces applied to it while in the vagina and during removal.

8. An apparatus according to any of claims 1-7 which is disposable.

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9. An apparatus according to any of claims 1-8 wherein said main body is adapted to not directly compress a urethra after said insertion.

10. An apparatus according to any of claims 1-9, wherein the ring shaped main body is provided with a varying degree of stiffness along its length enabling the main body to assume the predefined multi-planar shape upon insertion.

11. An apparatus according to any of claims 1-9 wherein the ring shaped main body elastically expands into the predefined multi-planar shape upon insertion.

12. An apparatus treating pelvic organ prolapse, comprising:

a main body adapted to provide pelvic organ support when inserted into a vagina; and,

an anchoring body, wherein said anchoring body is selectively affixed to said main body.

13. An apparatus according to claim 12 wherein said main body is non-planar, extending along three axes.

14. An apparatus according to claims 12 or 13 further comprising a device displacer.

15. An apparatus according to any of claims 12-14 further comprising a soft external layer located on at least a portion of said main body.

16. An apparatus according to any of claims 12-15 wherein said apparatus is adapted to be flexible in response to force applied on said apparatus while in said vagina and during removal from said vagina.

17. An apparatus according to any of claims 12-16 which is disposable.

18. An apparatus according to any of claims 12-17 wherein said main body is deformable upon the application of a removal force towards a vaginal opening.

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19. An apparatus according to any of claims 12-18 further comprising an applicator adapted for insertion of said apparatus.

20. An apparatus according to any of claims 12-19 wherein said anchoring body is ring shaped.

21. An apparatus according to any of claims 12-19 wherein said anchoring body is ovoid.

22. An apparatus according to any of claims 12-19 where said anchoring body is multi-sided.

23. An apparatus for treating pelvic organ prolapse, comprising:

a thin main body adapted to provide pelvic organ support when inserted into a vagina, which main body is deformable at at least three points thereon.

24. An apparatus according to claim 23 wherein said main body is non-planar, extending along three axes.

25. An apparatus according to claims 23 or 24 further comprising a device displacer adapted to impart movement to said apparatus.

26. An apparatus according to any of claims 23-25 further comprising a soft external layer located on at least a portion of said main body, said soft external layer adapted to prevent necrosis.

27. An apparatus according to any of claims 23-26 wherein said apparatus is adapted to be flexible in response to force applied on said apparatus while in said vagina and during removal from said vagina.

28. An apparatus according to any of claims 23-27 which is disposable.

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29. An apparatus according to any of claims 21-28 wherein said apparatus does not directly compress a urethra upon said insertion.

30. An apparatus according to any of claims 1-29 wherein said main body is provided with a hollow lumen, and further comprising:

a flexible tube, wherein said tube is attached to said main body and provided with a hollow lumen in fluid contact with said main body hollow lumen;

a non-compressible fluid located within the lumen proscribed by said tube and main body; and,

a blocking mechanism, wherein said blocking mechanism is slidably located on said tube thereby constraining said non-compressible fluid within said lumen.

31. An apparatus according to claim 30 wherein said flexible tube further comprises additional reservoir space, increasing the volume of the lumen proscribed by said tube and main body.

32. An apparatus according to any of claims 23-31 further comprising an applicator used for insertion of said apparatus.

33. A method of treating pelvic organ prolapse, comprising:

inserting into a vagina an apparatus for treating pelvic organ prolapse; and,

positioning said apparatus within said vagina wherein said apparatus exhibits a non-planar configuration after said insertion.

34. A method according to claim 33 wherein inserting is facilitated by using an applicator.

35. A method according to any of claims 33-34 further comprising removing said apparatus from said vagina.

36. A method according to claim 35 wherein said removal is facilitated by a device displacer adapted to impart movement to said apparatus.

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37. A method according to any of claims 33-36 further comprising disposing of said apparatus.

38. A method according to any of claims 33-37 wherein said positioning does not apply direct pressure to a urethra.

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